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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,823	10/15/2003	Peter C. Appelbaum	P50959RC2	7419

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT PAPER NUMBER

1614

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/685,823	Applicant(s) APPELBAUM	
	Examiner Kevin E. Weddington	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,8,10,12-23 and 27-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,9,11 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1-35 are presented for examination.

Applicants' preliminary amendment and information disclosure statement filed October 15, 2003 have been received and entered.

Applicants' election filed June 1, 2004 in response to the restriction requirement of May 6, 2004 has been received and entered. The applicants elected the invention described in claims 1, 2, 5-7, 9, 11 and 24-26 (Group I) with traverse. Claims 27-29 belong to Group II).

Applicants' traverse is not deemed persuasive for reasons set forth in the previous Office action dated May 6, 2004. Therefore, the restriction requirement is hereby made Final.

Claims 3, 4, 8, 10, 12-23 and 27-35 are being withdrawn from consideration as being drawn to the non-elected invention (37 CFR 1.142(b)).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5-7, 9, 11 and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is not seen where the instant specification enables the ordinary artisan to choose which derivative of gemifloxacin to use in the instant claims. The claims and specification

Art Unit: 1614

described modulating the metabolism of ciprofloxacin-resistant *Streptococcus pneumoniae* by using a gemifloxacin compound or a derivative thereof. However, the only enablement of “a gemifloxacin compound” or its derivatives is from PCT/KR98/0051 published as WO 98/42705 or EP 688772. However, these have not and cannot be incorporated into the specification. Due to this, the instant specification does not teach or enable the ordinary artisan to determine what is a “gemifloxacin compound” or “its derivatives”.

For rejections under 35 USC 112, first paragraph, the following factors must be considered (*In re Wands*, 8 USPQ2d 1400, 1404 (CAFA, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5-7, 9, 11 and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 5-7, 9, 11 and 24-26 are rendered indefinite and vague because the terms "gemifloxacin" and "ciprofloxacin" are Trademarks/common name for compounds. These names are defined in the specification. However, the names are not defined in the claims. The common name of a compound can change over time. So, what is now known, as ciprofloxacin may not be the same compound that will be known as ciprofloxacin in ten years. Due to this, it is suggested that the claims be amended to define ciprofloxacin and gemifloxacin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5-7, 9, 11 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong (5,633,262 and 5,776,944), Crabb (6,262,071), Hohl and Kim (all of PTO-1449).

Hong teaches gemifloxacin and its derivatives (see claim 1 for '944 and example 180, column 90 for '262). Gemifloxacin is a well-known antibacterial agent that shown a superior antibacterial activity in contrast to the known quinolone antibacterial agents against gram positive bacterial strains and also has a broad antibacterial spectrum and a highly improved pharmacokinetic property (see abstract '262). Hong teaches in '944, column 16, lines 21-32 that 'gemifloxacin' shows a potent and broad-spectrum antibacterial activity against various pathogenic organisms including gram-positive and gram-negative bacteria. The antibacterial activity of the present compound against gram-negative strains is comparable to or higher than that of the known antibacterial agents (for example, ciprofloxacin), and particularly, the antibacterial activity of the present compound against gram -positive strains is far superior to that of the known antibacterial agents. In addition, the present compound also exhibits a very potent antibacterial activity against the strains resistant to the known quinolone compounds.

Hohl and Kim both teach gemifloxacin and how it compared to other antibiotics. Crabb claims modulating metabolism of pathogenic bacteria by contacting the bacteria with gemifloxacin.

The instant invention differs from the cited references in that the cited references do not teach the gemifloxacin and its derivatives will modulate the metabolism of *streptococcus pneumoniae*. However, it would have been obvious to one skilled in the art that gemifloxacin


would modulate the metabolism of streptococcus pneumoniae over that of ciprofloxacin in the absence of evidence to the contrary.

Claims 1, 2, 5-7, 9, 11 and 24-26 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571) 272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
September 19, 2004